



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,577	08/27/2001	Roberto Defez	6242	6900

7590 07/29/2003

Samuels Gauthier & Stevens  
Suite 3300  
225 Franklin Street  
Boston, MA 02110

EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
----------	--------------

1636

10

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/831,577

Applicant(s)

DEFEZ ET AL.

Examiner

David A. Lambertson

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19, 20 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All   b) ☐ Some \*   c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.                      6) ☐ Other: \_\_\_\_\_

Art Unit: 1636

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group IV (Claims 19 and 20) in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

It is noted that in response to the restriction requirement, applicant added a new claim, indicated as Claim 21. However, there was already a Claim 21 present in the application at the time of election, drawn to an invention that was patentably distinct from the elected invention. As such, applicant's new claim has been renumbered to indicate that the claim is Claim 22, as per 37 CFR 1.126. Applicant should take note of this change when referring to the claim in the Office Action below, as well as in further communications.

Claims 1-22 are pending in the instant application. Claims 1-18 and 21 have been withdrawn as being drawn to a non-elected invention. Claims 19, 20 and 22 are ready for examination at the present time.

### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in this National Stage Application.

***Information Disclosure Statement***

The information disclosure statement filed August 27, 2001 as Paper No. 6 has been considered, and a signed and initialed copy of the form PTO-1449 is attached to this Office Action.

***Drawings***

New corrected drawings are required in this application because of the reasons set forth in the attached Draftsperson's review (form PTO-948). Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

***Specification***

A substitute specification excluding the claims is required pursuant to 37 CFR 1.125(a) because the specification is not in proper English grammar. The specification contains numerous grammatical errors and is virtually unreadable in a number of locations because of these errors. The specification must be in proper English so that the skilled artisan can read and understand the invention, however the instant specification does not accomplish this task. For example, the specification states on page 2, lines 5-8, "The promoter activity in Rhizobia of the *rolA* promintron resulted to be able to get gene expression in a novel and peculiar pattern within root nodules, resulting in a constitutive expression." This is simply an example, and is not inclusive

Art Unit: 1636

of all the errors in the specification. It is recommended that applicant fully review the specification and provide a specification that is understandable in order to further the prosecution of the application.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

---

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Specifically, the Abstract contains the improper legal language "said" in the second to last line of the Abstract. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 20 and 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection specifically addresses the written description issues regarding the promintron sequence to be used in the claimed invention.

Applicant claims the use of any promintron sequence homologous to that of SEQ ID NO: 1, or fragment thereof, to induce the expression of any DNA sequence so as to significantly increase the biomass of any plant. The claims read on a broad genus of promintron sequences and fragments thereof, and a broad genus of DNA sequences with the capacity to increase the biomass of any plant.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, the specification does not sufficiently describe a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics.

Art Unit: 1636

Applicant claims homologous promintron sequences and fragments of promintron sequences, as they relate to SEQ ID NO: 1, by function only, without any disclosed or known correlation between the elements and their function. The specification only provides teachings regarding the use of a single promintron sequence, SEQ ID NO: 1. The specification does not teach what fragments of this sequence would have the capacity to induce the expression of a DNA sequence such that it results in the increase of plant biomass, nor does the specification identify what portions of this sequence are required for its function as such. Furthermore, in the absence of such identifying characteristics, it would be impossible for the skilled artisan to envision what homologs of SEQ ID NO: 1 had the capacity to induce the expression of a DNA sequence in order to increase the biomass of a plant. Thus the skilled artisan could not envision what fragments of SEQ ID NO: 1 would be capable of inducing the expression of a gene, nor could the skilled artisan envision what homologs of SEQ ID NO: 1 would have this functional characteristic. Therefore, the skilled artisan cannot envision a sufficient number of embodiments of the instant invention from the instant specification because the specification only discloses a single embodiment, SEQ ID NO: 1, and provides no structure-function relationship for this sequence.

The prior art does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the prior art that allows one to envision a representative number of homologs or fragments of SEQ ID NO: 1 by disclosing structural or functional features of the sequence so that one of skill in the art could envision the claimed invention. Thus the skilled artisan cannot rely on the prior art to envision a sufficient

Art Unit: 1636

number of embodiments of the instant invention to see that the applicant was in possession of the claimed genus.

Neither the specification of the instant application or the prior art teaches a structure-function relationship for a representative number of species of the claimed genus. As a result, the skilled artisan would not be able to envision the claimed invention by relying on the teachings of the prior art or the instant specification. Therefore applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

Claims 19, 20 and 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection specifically addresses the written description issues regarding the DNA sequence that is induced to increase the biomass of a plant.

Applicant claims the use of any promintron sequence homologous to that of SEQ ID NO: 1, or fragment thereof, to induce the expression of any DNA sequence so as to significantly increase the biomass of any plant. The claims read on a broad genus of promintron sequences and fragments thereof, and a broad genus of DNA sequences with the capacity to increase the biomass of any plant.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical



Art Unit: 1636

properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, the specification does not sufficiently describe a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics.

Applicant claims the induction of any DNA sequence to result in the increase of plant biomass by function only, without any disclosed or known correlation between the elements and their function. The specification only provides teachings regarding the induced expression of the *iaaM* and *tms2* genes, specifically, and the increase of plant biomass in relation to their overexpression using the promintron sequence from the *rolA* gene (i.e., SEQ ID NO: 1). The specification does not teach what other genes can be overexpressed which would result in an increased plant biomass production, nor does the specification describe any rationale as to why the DNA sequence is irrelevant to the increase in plant biomass (as one of skill in the art would expect if any DNA sequence could be used in the invention). The specification indicates that the promintron sequence is merely a mechanism by which to induce the expression of the DNA sequence of interest, and that the genes that are expressed (and not the promintron sequence, per se) have the functional effect of increasing plant biomass. Therefore, the skilled artisan would presume that the gene that is expressed would be important with regard to the method that is claimed. However, the skilled artisan cannot envision a sufficient number of DNA sequences whose expression can be induced to result in an increased plant biomass from the instant specification because the specification only discloses the use of two very specific genes for this purpose. Therefore, the description in the specification does not provide a representative number

Art Unit: 1636

of genes that are sufficient to increase the plant biomass upon their induced expression, and does not satisfy the written description requirement as it relates to the broad genus that is claimed.

The prior art does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the prior art that allows one to envision a representative number of DNA sequences that, when induced by a promintron sequence, would result in an increased plant biomass. Therefore, one of skill in the art could not envision the claimed invention by relying on the prior art, and would not see that the applicant was in possession of the claimed genus.

Neither the specification of the instant application or the prior art teaches a structure-function relationship for a representative number of DNA sequences that, when their expression is induced by the *rolA* promintron sequence (SEQ ID NO: 1), have the capacity to increase the biomass of a plant. As a result, the skilled artisan would not be able to envision the claimed invention by relying on the teachings of the prior art or the instant specification. Therefore applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

Claims 19, 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of using SEQ ID NO: 1 to induce the expression of the *iaaM* and *tms2* genes to increase the biomass of a *Vicia hirsuta* plant, does not reasonably provide enablement for the use of any homolog or fragment of SEQ ID NO: 1 to induce the expression of any gene to increase the biomass of any plant. The specification does not enable

Art Unit: 1636

any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) the most relevant of which are discussed below:

**Nature of the invention.** The nature of the invention is a method of metabolic engineering, wherein a particular sequence (the promintron sequence) is used to induce the expression of a gene in a plant so that the biomass of the plant is increased relative to a plant wherein the expression of the gene is not induced by the promintron sequence. The invention involves effectively altering the metabolism of the plant so that its biomass is increased.

**Scope of the invention.** The scope of the invention is extremely broad on three fronts: (1) the sequence, a fragment or homolog of the described SEQ ID NO: 1, that can be used to induce the expression of a gene of interest; (2) the gene of interest that can be induced to result in an effective metabolic alteration in a plant so that the plant's biomass is increased significantly, relative to a plant where the gene is not induced; and (3) this can purportedly be done using any plant.

**State of the art.** The state of the art regarding the use of promintron sequences that are homologous or fragments of SEQ ID NO: 1 to induce the expression of a gene of interest is

Art Unit: 1636

silent. There is no description of SEQ ID NO: 1 in the prior art that would indicate what fragments of the sequence would have the activity to induce the expression of a gene, nor is there a description of homologs of SEQ ID NO: 1 that would have this activity. The art is also silent on what genes can be induced to effectively alter the metabolism of a plant such that the biomass of any plant is increased. In fact, the prior art reflects the unpredictability of such “metabolic engineering” as a whole, suggesting that the use of any gene in any plant would be unpredictable in terms of increasing the biomass of that plant. For instance, a review by Bailey (*Science* **252**: 1668-1674, 1991; see entire reference, especially the specific locations indicated below) points out several features that lead to areas of unpredictability regarding metabolic engineering.

Bailey indicates that “metabolic engineering is more a collection of examples than a codified science” and that although “[R]esults to date promise future technological benefits” many of the studies fall short of achieving practical results (see for example page 1668, third paragraph).

Bailey also points out that introduction of heterologous proteins may result in the appearance of unwanted or inhibitory compounds which can affect the metabolic engineering process, and that the expression of a given protein does not necessarily correlate to a desired function (see for example page 1668, fourth and fifth paragraphs). Bailey further indicates that such things as posttranslational modifications (see for example page 1668, eight paragraph) and co-factors (page 1669, bottom of the seventh paragraph) may also affect the metabolic engineering process in an unpredictable manner. In addition to Bailey, a reference by Parekh *et al.* (*Appl. Microbiol. Biotechnol.* **28**:287-301, 2000; see entire reference) also discusses the unpredictability that accompanies attempts at metabolic engineering. For example, Parekh states that metabolic engineering involves the empirical modification of metabolic pathways, most of which “are not

Art Unit: 1636

readily controllable or measurable due to the nature of metabolic transients or reaction fluxes” (see for example the paragraph bridging pages 287 and 289). Furthermore, Parekh that “with only limited knowledge of the physiology and genetics associated with the production of each molecule of interest, one is often led to an empirical approach to strain improvement”, suggesting that the improvement of strains in terms of metabolic engineering is unpredictable, and relegated to a case-by-case basis. For example, the metabolic engineering of each type of plant would either require explicit knowledge of each particular plant or a specific example of the engineering of each particular plant in order to overcome the unpredictability of metabolically engineering each plant. Although these references deal primarily with metabolic engineering as it concerns microorganisms, it is reflective of the unpredictability when practicing metabolic engineering in a more complex organism, such as a plant. This based on the rationale that metabolic engineering would not get any less complex as the organism that is being engineered becomes more complex. As a result of the lack of specific teachings regarding the metabolic engineering of plant cells to increase their biomass upon the induced expression of any gene, and the unpredictability associated with metabolic engineering as established by the Bailey and Parekh references, the skilled artisan would not be able to consult the prior art when attempting to make and use the invention as claimed, and would be forced to consult the instant specification for guidance and working examples.

**Number of working examples and Guidance provided by applicant.** The instant specification provides only one example of a promintron sequence that is capable of inducing the expression of a gene to increase the biomass of a plant, SEQ ID NO: 1. As indicated in the rejection under Written Description, the specification does not identify functional portions of the

Art Unit: 1636

promintron, so the skilled artisan would be unable to use homologs or fragments of SEQ ID NO:

1 because the skilled artisan would not be able to envision these homologs or fragments.

Similarly, the specification only indicates that using SEQ ID NO: 1 to induce the expression of two specific genes, *iaaM* and *tms2*, results in an increase in plant biomass. Thus the instant specification only provides limited teachings on the metabolic engineering of plants to increase their biomass. Furthermore, the specification only exemplifies the expression of these two genes using SEQ ID NO: 1 in a single plant species, *Vicia hirsuta*. As a result, the skilled artisan would only be able to make and use the invention in terms of this particular embodiment, there being no alternate teachings to support to full scope of the claimed invention, in either the specification or the prior art.

**Level of skill in the art.** The level of skill in the art of metabolic engineering of plants is highly underdeveloped, as supported by the Parekh and Bailey references indicated above, and in view of the limited teachings of the instant specification.

**Unpredictability of the art and Amount of experimentation required.** The invention, as claimed in terms of its broad scope set forth above, is highly unpredictable. The skilled artisan would only be apprised of a single promintron sequence, SEQ ID NO: 1, which could be used to induce the expression of a gene for the purpose of increasing the biomass of a plant. In order to identify fragments or homologs of this sequence having the required function, the skilled artisan would be forced to practice undue trial and error experimentation first to identify the functionally relevant portions of SEQ ID NO: 1, being given no guidance as to what portions are functionally relevant. The skilled artisan would then have to identify homologs having these functionally relevant portions, and test them for their actual ability to induce the expression of a gene.

Art Unit: 1636

Furthermore, the skilled artisan would have to practice unpredictable and undue trial and error experimentation to determine what genes would be able to affect the accumulation of plant biomass upon their induced experimentation. Finally, the skilled artisan would be required to determine the feasibility of this particular metabolic engineering event in all types of plants, including those that may not recognize the sequence of SEQ ID NO: 1 for promoter/enhancer activity (e.g., may not have the appropriate transcription factors) and those that may not have functional *iaaM* and *tms2* related pathways (e.g., downstream genes in the pathways to further metabolize the biochemical products obtained following expression of these genes). The unpredictability associated with this aspect of the invention is supported by the fact that metabolic engineering as a whole is unpredictable, that the instant specification only provides a single working example, and that there are literally millions of genes from different organisms that may or may not result in increased plant biomass upon their induced expression. Thus, the skilled artisan would be forced to undergo an enormous amount of experimentation to determine the enabled embodiments of the broadly claimed invention, especially in light of the guidance provided by the prior art and the instant specification. As a result, the invention is not enabled for the full scope in which it is claimed

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19, 20 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19, 20 and 22 are “Use” claims, and are indefinite for improperly defining a process. When claiming a process, it is proper to define the process as a “method of” in the preamble of the claim, followed by a recitation of the method steps involved in the process and a recapitulation step referring to the process as recited in the preamble of the claim. Without a recitation of the method steps, it is impossible to determine the metes and bounds of the claim. Furthermore, it is unclear as to whether or not the method is actually directed to the production of increased plant biomass or the induced expression of a gene, what steps are required to practice the invention, in what order the method steps must be performed in order to practice the method, or if the claims are indeed even directed to a method. In the interest of compact prosecution, and the examiners provisional determination of the metes and bounds of the claims for restriction purposes, it is determined that the claims are drawn to a method of increasing the production of plant biomass by inducing the expression of a DNA sequence using the promintron sequence identified as SEQ ID NO: 1, or fragments or homologs thereof.

Claims 19, 20 and 22 do not conform to proper English grammar, and are therefore difficult to understand as a whole. For example, the claims read on “a recombinant DNA molecule comprising a promintron sequence...said recombinant DNA molecule being covalently linked to the 3’ end of said promintron sequence...”; it is unclear how the molecule can be attached to something that it comprises, unless it is attached to itself in a never-ending cyclical manner. Additionally, the claim recites “said recombinant DNA molecule being covalently linked to the 3’ end of said promintron sequence, a DNA coding sequence...”; it is unclear if the promintron is a DNA coding sequence or if the DNA coding sequence refers to some other DNA coding sequence.



Claims 19, 20 and 22 are indefinite because they do not begin with an article, such as “A” or “The”. When properly indicating claimed subject matter, the claims should begin on a separate page with a statement such as “What is claimed is:” or “We claim:”, wherein each claim reads as a continuation of the sentence. Without the use of an article, the sentence would read, for example, ‘We claim use of...’, which is clearly not in proper grammatical form.

The term "significantly increase" in claims 19 and 22 is a relative term that renders the claim indefinite. The term "significantly increase" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For example, the skilled artisan would not understand if a 1% increase was a significant increase or not, or if a 90% increase was required for the increase to be significant. As such, the metes and bounds of the claim are unknown, and therefore indefinite.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 19, 20 and 21 are rejected under 35 U.S.C. 101 because the claims are “Use” claims, and are non-statutory because it is an improper definition of a process (see MPEP 2173.05(q)- “Use” claims). When claiming a process, it is proper to define the process as a “method of” in the preamble of the claim, followed by a recitation of the method steps involved in the process and a recapitulation step referring to the process as recited in the preamble of the claim.

Art Unit: 1636

***Allowable Subject Matter***


No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After-Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson  
July 27, 2003

  
PATENT EXAMINER  
A.U. 1636